IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ : FENFLURAMINE/DEXFENFLURAMINE) : PRODUCTS LIABILITY LITIGATION :

MDL DOCKET NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

ν.

AMERICAN HOME PRODUCTS CORPORATION

COM OMITTON

NO. 99-20593

THIS DOCUMENT RELATES TO:

Claimant: Jeryl Leaks Claim No.: 183/00

103,00

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8922

Bartle, J. August **8**, 2012

The Estate of claimant Jeryl Leaks, a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc., seeks benefits from the AHP Settlement Trust ("Trust"). Under the Settlement Agreement, Matrix Compensation Benefits ("Matrix Benefits") are awarded to compensate claimants for medical conditions caused by Pondimin or Redux ("Diet Drugs").

^{1.} Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease. See (continued...)

Mr. Leaks initially received Matrix A-1, Level III Benefits based on an April 20, 1999 echocardiogram which demonstrated severe aortic regurgitation, surgery to the aortic valve following Diet Drug usage, and ventricular fibrillation/sustained ventricular tachycardia. Thereafter, his Estate submitted a supplemental Green Form for Matrix Benefits based on the conditions shown in that echocardiogram and death as a result of valvular heart disease or valvular repair/replacement surgery. The Trust determined that the Estate was eliqible for benefits on the B Matrix because Mr. Leaks had not ingested Diet Drugs for at least 61 days as required for Matrix A Benefits under the Settlement Agreement. See Settlement Agreement, § VI.C.2.d. Because the Matrix A, Level III benefits which Mr. Leaks previously received exceeded the value of any supplemental Matrix B benefits, the Trust denied the claim on October 30, 2008.

Mr. Leaks's Estate claims that he ingested Diet Drugs for more than 60 days and is thus entitled to additional Matrix A

^{1.(...}continued)

Settlement Agreement, §§ IV.B.2.b. and IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious valvular heart disease who took the drugs for 61 days or longer and who did not have any of the alternative causes of the disease that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious valvular heart disease who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their heart disease was caused solely by the use of these Diet Drugs.

Benefits. As a result, the Estate filed an appeal for arbitration, and the court referred the matter to an arbitrator. See Settlement Agreement, § IV.C.4.h-I. The Arbitrator issued a Report and Award on August 8, 2011 affirming the Trust's determination that Mr. Leaks ingested the Diet Drugs for only 60 days.

Claimant has now appealed to this court as permitted under the Settlement Agreement. See id. Claimant's Estate argues that it provided sufficient information to the Trust to satisfy his burden of proof. We apply a clearly erroneous standard of review to the Arbitrator's findings of fact and conduct a plenary review of conclusions of law. First Options of Chicago, Inc. v. Kaplan, 514 U.S. 938, 947-49 (1995). The decision of this court is final and binding. See Settlement Agreement, § VI.C.4.1.

On appeal, the Estate asserts that it has submitted sufficient proof by Mr. Leaks under the Settlement Agreement to establish that he took Diet Drugs for more than 60 days. The relevant provision provides:

In order to complete the submission of a Claim and to qualify for any benefits under the Settlement Agreement, each Class Member must submit documentary proof to the Trustees and/or Claims Administrator(s) of the period of time for which the Diet Drugs Pondimin and/or Redux were prescribed and dispensed to the Diet Drug Recipient who is the subject of the Claim. This proof must include one of the following:

(1) If the diet drug was dispensed by a pharmacy, the identity of each pharmacy that dispensed Diet Drugs to the Diet Drug Recipient, including its name, address, and telephone number, and a copy of the prescription dispensing record(s) from each pharmacy, which should include the medication name, quantity and number of refills prescribed, prescribing physician's name, assigned prescription number, original fill date and each subsequent refill date; or,

- If the diet drug was dispensed directly by a physician or weight loss clinic, or the pharmacy record(s) is unobtainable, the identity of each prescribing physician, including the prescribing physician's name, address, and telephone number and a copy of the medical record(s) prescribing or dispensing the diet drug(s). The medical record(s) must include records which identify the Diet Drug Recipient, the Diet Drug name, the date(s) prescribed, the dosage, and duration the drug was prescribed or dispensed;
- (3) If the pharmacy records and medical records are unobtainable, an affidavit under penalty of perjury from the prescribing physician or dispensing pharmacy identifying the Diet Drug Recipient, the drug(s) prescribed or dispensed, the date(s), quantity, frequency, dosage and number of prescriptions or refills of the Diet Drug(s).

<u>See</u> Settlement Agreement, § VI.C.2.d. The burden of proving Diet Drug ingestion remains with the claimant. <u>See</u> Pretrial Order ("PTO") No. 7779 at 6 (Apr. 15, 2008).

Here, the Estate has submitted pharmacy records demonstrating that Mr. Leaks received two thirty-day supplies of

Pondimin: one prescription on April 3, 1997 for 20 mg Pondimin once daily and another prescription on June 20, 1997 for 20 mg Pondimin three times per day. These records create a rebuttable presumption that Mr. Leaks ingested Diet Drugs for 60 days. The Estate also produced medical records which demonstrate that two thirty-day supplies of Pondimin were dispensed to Mr. Leaks.

The other materials on which the Estate relies are insufficient to rebut this presumption. The Blue Form

Declaration signed by Mr. Leaks's dispensing pharmacist Casey

Canon, which suggests that Pondimin was continuously prescribed to Mr. Leaks from April 3, 1997 through August 1, 1997, is contradicted by the pharmacy and medical records. The letter of Mr. Leaks's prescribing physician, Dr. Edison Rodrigues, is not an affidavit signed under penalty of perjury and is thus insufficient to rebut the presumption that Mr. Leaks ingested Diet Drugs for only 60 days. Similarly, the affidavit of Mr. Leaks's widow, Louisa Leaks, is insufficient because it is from an interested party and not corroborated by other credible evidence. See PTO No. 3261 at 5-6 (Feb. 13, 2004).

Finally, claimant's Estate asserts that it is entitled to Matrix A Benefits based on Mr. Leaks's earlier receipt of benefits at that level. However, those benefits were paid according to the Parallel Processing Program ("PPP") approved by

^{2.} We further note that the Settlement Agreement provides for the submission of an affidavit from the prescribing physician only when pharmacy and medical records are not available. <u>See</u> Settlement Agreement, § VI.C.2.d.3. That is not the case here.

this court in PTO No. 3882. Under the PPP, when claims are designated by Wyeth as payable, "[t]he Trust shall not run the Green Form algorithm, require additional completeness steps, or conduct any additional review of the claim, but instead shall process the claim at the level and amount specified in Wyeth's designation." See PTO No. 3882 (Aug. 26, 2004). Thus, under the plain terms of the PPP, the Trust did not make any determination regarding the duration of Mr. Leaks's Diet Drug usage in connection with the payment of his earlier claim.

Accordingly, the Arbitrator's award was not clearly erroneous as to his findings of fact, and he did not err as to his conclusions of law. The Report and Award of the Arbitrator will be affirmed.